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February 12, 2019

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

Test substance:

8EHQ-19-21622

1-Propene, 1,1,2,3,3,3-hexafluoro-
CAS RN 116-15-4

This letter is to inform you of the results of the following developmental study with the above-referenced test substance. This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, because it is information in which EPA may have an interest.

The objective of this study was to provide data on the possible effects of the test substance on pregnant female New Zealand White rabbits and the development of the embryo and fetus consequent to daily inhalation exposure to the test substance from gestation day (GD) 6 up to and including gestation day 28.

Animals were exposed to test atmospheres in whole body exposure chambers for 6 hours per day at concentrations of 0, 10, 50 and 300 ppm hexafluoropropene (HFP). The overall average actual concentrations (± standard deviation) of HFP in the test atmospheres, as determined by total carbon analysis, were 9.98 (± 0.28), 50.5 (± 1.3) and 304 (± 8) ppm for the low-, mid and high-concentration groups, respectively. These concentrations were close to the respective target concentrations of 10, 50 and 300 ppm.

Each group comprised of 22 mated females and in-life parameters included mortality and morbidity, body weight and food consumption. At gestation day 29 caesarean section was performed on the animals in all groups and necropsy parameters included examination of the dams for gross anatomical changes, uterus and ovary weight. The number and distribution of implantation sites, live and dead fetuses and resorptions were recorded. In addition, placentas and live fetuses were weighed individually.

Fetuses from all groups were examined for external and visceral malformations. After visceral examination, the fetal bodies were processed and stained with Alzarin Red S. for skeletal examination. Heads of half of the fetuses in each litter were fixed in Bouin's fixative for visceral head examination.

Daily exposure to 0, 10, 50 and 300 ppm HFP from gestation day 6 up to and including day 28 in New Zealand White rabbits resulted in:

- One animal in the 10 ppm group died spontaneously. No other mortality or treatment related morbidity were observed.

- Statistically significant, but not biologically adverse lower body weight was observed in the 300 ppm group at days 12 and 15 compared to the control group.
- Statistically significant, but not biologically adverse lower body weight gain was observed as compared to the control group from GD 6-9 and GD 9-12 in the high concentration group (300 ppm).
- Food intake was decreased in the high concentration group from GD 6-9, GD 9-12 and GD 12-15, whereas in the low and mid concentration groups no effects were observed on body weight or food consumption.
- No treatment-related maternal macroscopic deviations were observed.
- No effects on the mean number of corpora lutea, the number and distribution of implantation sites, live or dead fetuses, and early and late resorptions were observed.
- No effects on the mean fetus weight in both male and female fetuses were observed.
- Fetal external and visceral examinations showed no treatment-related effects.
- A slight retardation in ossification was observed in fetuses in the 300 ppm group. This was considered a treatment-related effect, but not adverse.

Conclusions:
There were no treatment-related adverse effects at any concentration. Therefore, the No Observed Adverse Effect Concentration for maternal toxicity was placed at 300 ppm HFP. Delayed ossification (a variation) was observed at 50 ppm, but there were no treatment-related adverse effects at any concentration. Therefore, the No Observed Adverse Effect Concentration for developmental toxicity was placed at 300 ppm.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Substantiation of our claim of confidentiality is included herewith as **Attachment 1**. Please contact me if you have any questions about this submission or need further clarification.

Sincerely,

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Attachment 1

Entire Substantiation Claimed as Confidential Business Information